THINK Surgical, Inc.
Meliha Mulalic
Director, Regulatory Affairs and Quality Assurance
47201 Lakeview Blvd
Fremont, California 94538

October 8, 2019

Re: K191369
Trade/Device Name: TSolution One Total Knee Application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 6, 2019
Received: September 9, 2019

Dear Meliha Mulalic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191369

Device Name
TSolution One® Total Knee Application

Indications for Use *(Describe)*

The TSolution One® Total Knee Application is intended for use as a device that uses diagnostic images of the patient acquired specifically to assist the physician with preoperative planning and to provide orientation and reference information during intraoperative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool are used as an alternative to manual planning and resecting techniques for the distal femur and proximal tibia preparation in primary total knee arthroplasty (TKA).

The TSolution One Total Knee Application is indicated for orthopedic procedures in which resecting techniques used for the distal femur and proximal tibia may be considered to be safe and effective and where references to rigid anatomical structures may be made.

The TSolution One® Total Knee Application is also intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The TSolution One® Total Knee Application facilitates accurate positioning of TKA implants, relative to these alignment axes.

The TSolution One® Total Knee Application is compatible with the Zimmer Persona™ Knee System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Applicant Information:

Owner Name:	THINK Surgical, Inc.
Address:	47201 Lakeview Blvd., Fremont, CA 94538
Phone number:	510-249-2337
Fax number:	510-249-2396
Establishment Registration Number:	3000719653
Contact Person:	Meliha Mulalic
Date Prepared:	May 20, 2019

Device Information:

Device Classification:	Class II
Trade Name:	TSolution® One Total Knee Application
Common name:	Orthopedic Stereotaxic Instrument
Classification name:	Stereotaxic Instrument
Regulation number:	882.4560
Product Code:	OLO

Predicate Device:
The TSolution® One Total Knee Application is substantially equivalent in intended use, fundamental scientific technology and performance to the following legally marketed device in commercial distribution: THINK Surgical, Inc's TSolution One® Surgical System Model 210 cleared under K170430. The difference between the new device and the predicate is that the new device introduces a new indication for use for total knee arthroplasty and provides the tools and modified software for the preparation of the bone for this indication.

Device Description:
The TSolution One® Total Knee Application is a three-dimensional, graphical, preoperative planner and implementation tool for treatment of patients who require total joint arthroplasty. The device is intended as an alternative to manual template planning and preparation of the bone with patients requiring primary total knee arthroplasty (TKA).

The TSolution One® Total Knee Application consists of TPLAN and TCAT. TPLAN is a three-dimensional (3D) preoperative planning workstation that aids a surgeon in planning the position and orientation of the implant components relative to 3D models of the patient's anatomy. TCAT consists of an electromechanical arm, an

arm base including control electronics and computer, a display monitor, operating software, pendant control, and tools and accessories, for the implementation of the preoperative plan. TCAT and TPLAN when used according to the instructions for use, make submillimeter precision bone preparation possible before and during TKA surgical procedures.

Intended Use / Indications for Use:
The TSolution One® Total Knee Application is intended for use as a device that uses diagnostic images of the patient acquired specifically to assist the physician with preoperative planning and to provide orientation and reference information during intraoperative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool are used as an alternative to manual planning and resecting techniques for the distal femur and proximal tibia preparation in primary total knee arthroplasty (TKA).

The TSolution One® Total Knee Application is indicated for orthopedic procedures in which resecting techniques used for the distal femur and proximal tibia may be considered to be safe and effective and where references to rigid anatomical structures may be made.

The TSolution One® Total Knee Application is also intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The TSolution One® Total Knee Application facilitates accurate positioning of TKA implants, relative to these alignment axes.

The TSolution One® Total Knee Application is compatible with the Zimmer Persona™ Total Knee System.

Substantial Equivalence:
Both the TSolution One® Total Knee Application, and the predicate device, the TSolution One Surgical System Model 210 have the same intended use. Both are intended for use as a device that uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intraoperative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan. The difference between the new device and the predicate are that the new device introduces a new indication for use for TKA and provides the tools and modified software for the preparation of the bone for this indication.

The new indication for use of the device for total knee arthroplasty does not raise any new types of safety and effectiveness questions. The types of questions for the changes made raise the same questions as for the cleared indication for total hip arthroplasty and are addressed by similarities in materials, technological characteristics, operational principles, and performance testing. Additionally, clinical testing of the new device consisted of a multicenter clinical study to demonstrate the safety and effectiveness of

the TSolution® One Total Knee Application for total knee arthroplasty. Furthermore, the Mako Surgical Corp. RIO for Total Knee Application (K143752) has the same intended use as the TSolution One® Total Knee Application, similar operational principles and has a cleared indication for use in total knee arthroplasty.

Substantial equivalence in technological characteristic and performance of the TSolution One® Total Knee Application to the predicate device, TSolution One Surgical System Model 210 is outlined in the table below:

Product	**TSolution One Total Knee Application**	**TSolution One Surgical System Model 210**	**Conclusion**
510(k) number	K191369 (Subject Device)	K170430	
Manufacturer	Think Surgical Inc	Think Surgical Inc	
Technological Characteristics			
-Patient Imaging	CT Scan	CT Scan	**SAME**
-User Controls	Keyboard, mouse, Pendant with mechanically latched Stop Button	Keyboard, mouse, Pendant with mechanically latched Stop Button	**SAME**
-Preoperative planning workstation	TPLAN three-dimensional preoperative planning workstation	TPLAN three-dimensional preoperative planning workstation	**SAME**
-Pre-surgical Plan	CT images used to create a 3D model of the bone, library of FDA cleared components used to develop optimal implant size and location	CT images used to create a 3D model of the bone, library of FDA cleared components used to develop optimal implant size and location	**SAME**
-Surgical Plan Data	High level operative plan based on preoperative plan with predetermined control file developed to control the robotic arm.	High level operative plan based on preoperative plan with predetermined control file developed to control the robotic arm.	**SAME**
-Surgical Exposure	Similar to traditional surgical exposure for the anatomic site	Similar to traditional surgical exposure for the anatomic site	**SAME**
Electromechanical arm to implement pre-surgical plan	TCAT electromechanical arm system implements pre-surgical plan	TCAT electromechanical arm system implements pre-surgical plan	**SAME**

Product	TSolution One Total Knee Application	TSolution One Surgical System Model 210	
510(k) number	K191369 (Subject Device)	K170430	
Manufacturer	Think Surgical Inc	Think Surgical Inc	**Conclusion**
-Patient/Robot Registration	Pinless point to surface registration with mechanical tracking. Percutaneous probe thin enough to make contact via direct puncture through skin.	Pinless point to surface registration with mechanical tracking. Percutaneous probe thin enough to make contact via direct puncture through skin.	**SAME**
-Bone Motion Recovery	Two bone motion recovery markers are used to recover registration after bone motion.	Two bone motion recovery markers and percutaneously located distal band regions used to recover registration after bone motion.	**Substantially Equivalent** (Distal band only required to track tip of femoral hip component – not required for knee)
Performance Testing			
-Biocompatibility	Passed	Passed	**SAME**
-Cutting Accuracy	Tested to Meets User requirements - PASSED	Tested to Meets User Requirements - PASSED	**Substantially Equivalent**
-Cadaver Lab Validation Testing	Passed	Passed	**SAME**
-Software Testing	Verify TPLAN presurgical planning and TCAT Surgical System Software function successfully to complete procedure- PASS	Verify TPLAN presurgical planning and TCAT Surgical System Software function successfully to complete procedure - PASS	**SAME**
Electromagnetic Compatibility and Electrical Safety	Meets IEC Requirements	Meets IEC Requirements	**SAME**

Clinical Testing:
The TSolution One Total Knee Application clinical trial was designed as a multi-center, prospective, non-randomized clinical trial to evaluate the safety and effectiveness of TSolution One Total Knee Application compared to a historical control for orthopedic procedures of the knee requiring a primary unilateral total knee arthroplasty (TKA). Enrolled subjects had a confirmed Kellgren-Lawrence Grade of 3 or higher, had not undergone previous open knee surgery in the operative knee, and did not have a coronal deformity greater than 20 degrees, or a sagittal flexion contracture greater than 15 degrees.

The study was carried out at six investigational sites in the US with eight clinical investigators. A total of 115 patients were enrolled in the study and constitute the intent to treat group. Subject age ranged from 43.0 to 85.0 years old, with a mean age of

65.91. These results are reflective of the expected TKA patient population, which tends to be older. The mean BMI for subjects was 30.71. Subjects were 50.4% male and 49.6% female and the majority of patients had never smoked (72.2%). The most common comorbidity was cardiovascular conditions (71.2%), followed by musculoskeletal conditions (41.3%). Eleven subjects did not have any comorbidities and none of the comorbidities constituted an exclusion criteria or contraindication for surgery.

The primary endpoints include components that address safety and effectiveness. The primary safety endpoint was a composite safety endpoint that includes seven relevant adverse events that were defined and published by the Knee Society, each having an expected incidence ≤2.7%. The sum of these relatively rare complications is equal to 7.6%. The percentage of patients with TCAT-assisted implantation using the TSolution One Total Knee Application experiencing the composite safety event was compared to 7.6%. None of the seven adverse events identified were observed in the study. A total of 115 out of 115 patients (100%) successfully completed the primary safety endpoint.

The primary effectiveness endpoint was alignment of coronal mechanical axis at 3 months defined as achieving varus-valgus alignment after TKA that is less than ±3° from the preoperative plan in the frontal plane. A review of 1,376 patients undergoing conventional TKA with manual instrumentation showed a 32% malalignment rate for neutral mechanical axis deviation greater than 3°. The study was designed to demonstrate that the investigational device is capable of reducing the malalignment rate by 50%, i.e. to 16%.

With respect to the primary effectiveness endpoint, all 115 patients were evaluated at 3 months. The study population saw a low malalignment rate of 13.0% (15 out of 115 ITT patients) and 11.2% (12 out of 107 PP patients) which equates to a reduction of 59.2% (ITT) and 65.0% (PP) compare to 32% malalignment rate reported in literature. The study does provide significant data to demonstrate with a high probability (0.958) that the TSolution One Total Knee Application achieved a 37.2% (ITT) and a 43.1% (PP) reduction in the malalignment rate. The overall effectiveness results for the data presented demonstrate that the robotic-assisted TKA with TSolution One Total Knee Application is an effective treatment and helped to substantially reduce the overall malalignment rates in comparison to manual TKA.

Subsequent and supportive endpoints further demonstrate the effectiveness of the TSolution One Total Knee Application. The secondary radiographic outcomes (TJLA, FJLA, Tibial Slope) showed an ability of the system to match the pre-op plan. The KSS and SF-12 components showed a positive and comparable outcome in comparison to other TKA performed in the literature.

A review of adverse events further supported the safety of the device. There were 34 adverse events that were considered possibly, probably, or definitely related to the device or procedure. The most commonly occurring of these were: Pain, Excessive or Unexpected (6 subjects), Edema, Excessive or Unexpected (5 subjects), Fall (4 subjects) and Rash and Stiffness of the Joint (3 subjects each). There was a case in which two recovery markers (tacks) were left in the subject. However, the event did not require surgery and the patient showed good clinical outcomes out to 12 months. There were only five device related adverse events. Of those five, three were SAEs. These same three SAEs were also reported as Device or Procedure Related SAEs. All three

events were classified as “Stiffness of the joint” and were resolved through manipulation under anesthesia (MUA). There were no serious adverse events (0%) classified as definitely related to the device. No subject required a surgical intervention related to the TKA.

In conclusion, the data from this clinical trial demonstrate that the TSolution One Total Knee Application in comparison to conventional manual surgical TKA has a positive risk-benefit profile and is both safe and effective for use in a TKA patient population.

Conclusion

The TSolution One® Total Knee Application is equivalent to the predicate, TSolution One Surgical System Model 210 in the following ways: it has the same intended use, the same technological characteristics and operating principles, incorporates the same basic design and incorporates the same or similar materials. The results of performance testing demonstrate that the TSolution One® Total Knee Application performed substantially equivalent to the predicate and did not raise any new questions of safety and effectiveness. Clinical data further supports the safety and effectiveness of the TSolution One® Total Knee Application and demonstrated a positive risk/benefit for the indication for use in total knee arthroplasty. The data presented supports a determination of Substantial Equivalence.